IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

INDIVIOR INC. *f/k/a* RECKITT BENCKISER PHARMACEUTICALS INC., and AQUESTIVE THERAPEUTICS, INC. *f/k/a* MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC. Defendant.	Civil Action No.: 5:15-cv-00350-D **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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Plaintiffs Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), and Aquestive Therapeutics, Inc. ("Aquestive") f/k/a MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") hereby file this First Amended Complaint against Defendant BioDelivery Sciences International, Inc. ("BDSI" or "Defendant"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 8,765,167 ("the '167 patent"), attached hereto as Exhibit A, arising under the Patent Laws of the United States, Title 35 of the United States Code.

2. Defendant BDSI has marketed and sold BUNAVAIL™ (buprenorphine/naloxone) buccal film ("BUNAVAIL"), which is a pharmaceutical drug product that infringes at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118 of the '167 patent.

BACKGROUND

3. Defendant BDSI submitted a New Drug Application under 21 U.S.C. § 355(b)(2) (the "505(b)(2) NDA") to the FDA seeking approval to manufacture, market and sell an infringing pharmaceutical drug product BUNAVAIL™ ("BUNAVAIL") throughout the United States, including in this Judicial District. BDSI's NDA was approved on June 6, 2014 for the maintenance treatment of opioid dependence.

4. On November 3, 2014, BDSI announced that BUNAVAIL was "anticipated to be available by prescription at retail pharmacies across the U.S. by the end of this week." *See* Ex. D ("BioDelivery Sciences Announces the Availability of BUNAVAIL™ in the U.S.," November 3, 2014).

5. BDSI has had knowledge of the '167 patent since at least September of 2014 when Indivior and Aquestive filed the present suit against BDSI for infringement of the '167 patent by

BDSI's BUNAVAIL buccal film.

6. With full knowledge of the '167 patent, BDSI continued to willfully market and sell its infringing BUNAVAIL buccal film. On information and belief, BDSI's willful infringement continued for at least over six years until June 2020. *See* Ex. C (BDSI 2020 10-K SEC Filing) at p. 11 ("We discontinued all marketing of BUNAVAIL in June 2020, however the NDA remains active."). On information and belief, despite BDSI allegedly ceasing to market its BUNAVAIL buccal film product, BDSI continued to willfully sell its infringing BUNAVAIL buccal film. *Id*; *see also* Ex. E (March 4, 2021 BUNAVAIL FDA Label).

THE PARTIES

7. Plaintiff Indivior, Inc. (f/k/a) RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

8. Plaintiff Aquestive Therapeutics, Inc. (f/k/a MonoSol) is a Delaware corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

9. Upon information and belief, Defendant BDSI is a Delaware corporation having a principal place of business at 4131 Parklake Ave., Suite 225, Raleigh, North Carolina, 27612.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b) at least because BDSI had committed, and on information and belief, continues to commit acts of patent infringement in this District and has a regular and established place of business in the Eastern District of North Carolina.

12. This Court has personal jurisdiction over BDSI because of, *inter alia*, BDSI's principal place of business in North Carolina; BDSI's continuous and systematic contacts with

corporate entities within this Judicial District; BDSI's purposeful availment of the benefits and protections of the laws of North Carolina; and BDSI's marketing and sales activities in this Judicial District, including but not limited to, the substantial, continuous, and systemic distribution, marketing, and/or sales of pharmaceutical products—including BUNAVAIL—to residents of this Judicial District.

THE '167 PATENT

13. Aquestive is a specialty pharmaceutical company that uses its proprietary PharmFilm® technology to deliver drugs in films. Through years of research and development, Aquestive has obtained over 200 patents and several FDA approvals.

14. On July 1, 2014, the '167 patent, entitled "Uniform Films for Rapid-dissolve Dosage Form Incorporating Anti-tacking Compositions," was duly and legally issued to inventors Garry L. Myers, Pradeep Sanghvi, Andrew Philip Verrall, Vimala Francis, and Laura Moss. That patent was assigned to Aquestive. *See* Ex. A.

15. The '167 patent generally relates to rapidly dissolving films that incorporate anti-tacking agents and/or that contain an active component—such as a drug—that is evenly distributed throughout the film. *See, e.g.*, Ex. A at Abstract. Oral films have several advantages as alternatives to tablets, pills, and the like. *See, e.g.*, *id*. at 1:26-47.

16. The inventors of the '167 patent conceived of pioneering improvements in the making of films, improvements that enable uniform distribution of components therein and that prevent undesired aggregations of components in the final film product. Their improvements are set forth in the claims of the '167 patent. For example, Claim 95 recites:

> An oral film for delivery of a desired amount of an active component comprising:
>
> an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethylcellulose,

hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;

at least one anti-tacking agent comprising sodium benzoate;

a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof, said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;

wherein said film is self-supporting and the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.

17. Aquestive presently, and during all relevant times, owns all rights, title, and interest to the ’167 patent, including the right to sue and to recover for any current or past infringement of that patent by BDSI’s BUNAVAIL buccal film.

18. Indivior (f/k/a RBP) is an exclusive licensee of Aquestive for the ’167 patent.

BDSI’S INFRINGING BUNAVAIL BUCCAL FILM

19. BDSI’s BUNAVAIL product is a mucoadhesive, polymer film that dissolves in the mouth.

20. BUNAVAIL is sold in three nominal strengths: 2.1 mg buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone; and 6.3 mg buprenorphine/1.0 mg naloxone.

21. BDSI makes, or directs the making of, BUNAVAIL. *See e.g.*, Ex. C (BDSI 2020 10-K SEC Filing) at p. 18 (“In 2020, we utilized only one contract manufacturer to create the BELBUCA and BUNAVAIL laminates and an additional two contract manufacturer to package the laminates into final product.”); Ex. K (BDSI 2013 10-K SEC Filing) at p. 13 (“For BUNAVAIL™, we have certain manufacturing arrangements in place on a purchase order basis and will seek to secure long term supply contracts as we move closer to potential FDA approval

and commercial launch. We also have relationships with third party contract research organizations that assist us with the management of our clinical trials.").

22. BDSI directs all development, marketing, and promotional activities relating to BUNAVAIL from its headquarters in Raleigh, North Carolina. *See* Ex. B (December 12, 2014 Declaration of Andrew L. Finn, Pharm. D., Civil Action No. 3:14-cv-05892 MAS-TJB, Dkt. No. 13-17).

23. BDSI has had marketed, and currently sells, and offers for sale BUNAVAIL in the United States, for the maintenance treatment of opioid dependence. Ex. C (BDSI 2020 10-K SEC Filing) at p. 28 ("We recognized $154.6 million and $107.9 million in product sales during the years ended 2020 and 2019, respectively, from our products BELBUCA, Symproic and BUNAVAIL."); *id*. at 13 ("[I]n June 2020, we subsequently discontinued marketing for BUNAVAIL.").

24. BUNAVAIL uses BDSI's BioErodible MucoAdhesive ("BEMA") technology which "uses a small polymer film applied to the inner lining of the cheek for rapid drug administration." *See* Ex. F (BDSI BEMA webpage); Ex. C (BDSI 2020 10-K SEC Filing) at p. F-36 ("On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the ''843 Patent') relating to the BEMA technology, and this patent was properly listed in the Orange Book as covering the BUNAVAIL buccal film.").

25. BUNAVAIL is a buccal film that provides transmucosal delivery of buprenorphine, a partial opioid agonist, and naloxone, an opioid antagonist. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 11 "Description" ("BUNAVAIL (buprenorphine and naloxone) buccal film is a citrus flavored oral transmucosal form of buprenorphine, an opioid partial agonist, and naloxone, an opioid antagonist, intended for application to the buccal mucosa."); *see also* Ex.

E (March 4, 2021 FDA Prescribing Information) at § 11.

26. BUNAVAIL is available in three strengths "2.1 mg buprenorphine with 0.3 mg naloxone in a 2.2 cm^2 film; 4.3 mg buprenorphine with 0.7 mg naloxone in a 4.4 cm^2 film; and 6.3 mg buprenorphine with 1 mg naloxone in a 6.5 cm^2 film." *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 11 "Description"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at § 11.

27. The active ingredients in BUNAVAIL are buprenorphine HCl, a mu-opioid receptor partial agonist and a kappa-opioid receptor antagonist, and naloxone HCl dihydrate, an opioid receptor antagonist. *Id*. at § 11 "Description." BUNAVAIL also contains "carboxymethylcellulose sodium, citric acid, citrus blend flavor, dibasic sodium phosphate, blue ink, hydroxyethyl cellulose, hydroxypropyl cellulose, methylparaben, monobasic sodium phosphate, polycarbophil, propylene glycol, propylparaben, yellow iron oxide, sodium benzoate, sodium hydroxide, sodium saccharin, vitamin E acetate, and purified water." *Id*. The blue ink contains FD&C blue #1, ethanol, purified shellac, acetone, ammonium hydroxide and water. *Id*.

28. The FDA's Approved Drug Products with Equivalence Evaluations (commonly known as the Orange Book) listing for BUNAVAIL identifies four patents, including United States Patent Nos. 8,147,866 ("the '866 patent"), 8,703,177 ("the '177 patent"), 9,522,188 ("the '188 patent"), and 9,655,843 ("the '843 patent"), all of which are assigned to BDSI. True and correct copies of the '866 patent, the '177 patent and the '843 patent are attached hereto as Exhibits H, I and J, respectively.

29. The '866 patent, the '177 patent, and the '843 patent are all directed to BDSI's BEMA process used in manufacturing of the BUNAVAIL buccal films. *See* Ex. C (BDSI 2020 10-K SEC Filing) at p. 9 ("In April 2012, the USPTO granted US Patent No. 8,147,866, which

will extend the exclusivity of the BEMA drug delivery technology for BELBUCA and BUNAVAIL in the United States from 2020 to 2027. In April 2014, the USPTO granted US Patent No. 8,703,177 (issued from US Patent Application No. 13/590,094), which will extend the exclusivity of the BEMA drug delivery technology for BUNAVAIL in the United States to at least 2032. [ ] We own various patents and patent applications relating to the BEMA technology. US Patent No. 6,159,498 (expiration date October 2016), US Patent No. 7,579,019 (expiration date January 22, 2020), US Patent No. 8,147,866 (expiration date July 23, 2027) …"); *see also id*. at F-36 ("On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the ''843 Patent') relating to the BEMA technology, and this patent was properly listed in the Orange Book as covering the BUNAVAIL buccal film.").

30. The '866 and '843 patents describe manufacturing processes for films containing buprenorphine, including mixing the ingredients for a backing layer (Exhibit H ('866 patent) at 19:21-39; Exhibit J ('843 patent) at 19:50-20:2), mixing the ingredients for a mucoadhesive layer (Exhibit H ('866 patent) at 19:40-20:3; Exhibit J ('843 patent) at 20:3-34), and the following casting and drying procedures:

> The layers were cast in series onto a St. Gobain polyester liner. First, the backing layer was cast using a knife-on-a-blade coating method. The backing layer was then cured in a continuous oven at about 65 to 95° C. and dried. After two coating and drying iterations, an approximately 8 mil (203 to 213 micrometers) thick backing layer is obtained. Subsequently, the mucoadhesive polymeric diffusion environment was cast onto the backing layer, cured in an oven at about 65 to 95° C. and dried. The devices were then die-cut by kiss-cut method and removed from the casting surface.

Exhibit H ('866 patent) at 20:4-13; Exhibit J ('843 patent) at 20:35-44.

31. The '866 and '843 patents further describe the ingredients used in the films, including that the films contain sodium benzoate in an amount equal to "about 0.06% total formulation, by weight." Exhibit H ('866 patent) at 19:44; Exhibit J ('843 patent) at 20:7-8.

32. The ’866 and ’843 patents further describe the use of polymers to slow or stop the flux of medicament in the films such that “there is typically not free flux of the medicament in all directions” (Exhibit H (’866 patent) at 6:33-49; Exhibit J (’843 patent) at 6:48-64), and describes that the flux of medicament occurs only once the film is applied to mucosa (*see, e.g.*, (Exhibit H (’866 patent) at 6:40-45 and Exhibit J (’843 patent) at 6:55-60 (“Upon mucoadministration, a gradient is created between the mucoadhesive polymeric diffusion environment and the mucosa, and the medicament flows from the mucoadhesive polymeric diffusion environment, substantially in one direction towards the mucosa.”); (Exhibit H (’866 patent) at 15:24-27 and Exhibit J (’843 patent) at 15:50-53 (“dissolution or erosion of the barrier environment and/or backing layer primarily controls the directionality of medicament flow from the device of the present invention after application to the mucosa”).

33. The ’177 patent describes the structure of the BUNAVAIL buccal films:

> In some embodiments, the mucoadhesive layer is a bioerodable or water-erodable mucoadhesive layer. In some embodiments, the devices of the present invention include a bioerodable mucoadhesive layer which comprises a mucoadhesive polymeric diffusion environment. The device adheres to a mucosal surface of the subject within about 5 seconds following application.

Exhibit I (’177 patent) at 8:29-36.

> The device further comprises at least one additional non adhesive polymeric environment, e.g., a backing layer. This layer is disposed adjacent to the mucoadhesive polymeric diffusion environment, e.g., a backing layer, functions to facilitate the delivery of the opioid agonist, Such as buprenorphine, to the mucosa. This additional layer may comprise the same or a different combination of polymers as the mucoadhesive polymeric diffusion environment or the non-adhesive polymeric diffusion environment.

Exhibit I (’177 patent) at 10:13-21.

COUNT I
(Infringement of the U.S. Patent No. 8,765,167)

34. Plaintiffs incorporates each of the preceding paragraphs 1-33 as if fully set forth herein.

35. BDSI has infringed, and on information and belief, continues to infringe, the '167 patent by making, using, offering to sell, and/or selling within the United States, products that practice the inventions of the '167 patent, including, but not limited to BDSI's BUNAVAIL buccal film products. BDSI's BUNAVAIL buccal film products literally infringe at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

36. More specifically, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 13 of the '167 patent as follows:

a. Claim 13 recites "[a]n oral film for delivery of a desired amount of an active component comprising."

i. Regardless of whether the preamble is limiting, BDSI's BUNAVAIL buccal film literally infringes the preamble.

ii. BDSI's BUNAVAIL buccal film is "applied to the buccal mucosa." *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 2.1; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at § 2.1.

iii. BDSI's BUNAVAIL buccal film delivers buprenorphine and naloxone in the desired dosage amount (2.1 mg / 0.3 mg, 4.2 mg / 0.7 mg, or 6.3 mg / 1 mg (buprenorphine/naloxone)) in an "oral transmucosal form." *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 11 (Description) *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at § 11.

iv. BDSI's BUNAVAIL buccal film contains buprenorphine hydrochloride and naloxone hydrochloride dihydrate as the active ingredients. *See id.* at "Medication Guide" ("**Active ingredients:** buprenorphine hydrochloride, naloxone hydrochloride dihydrate.").

b. Claim 13 further recites "an ingestible, water-soluble polymer matrix comprising at least one polymer selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose, polyethylene oxide and combinations thereof;"

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film uses BDSI's BEMA "technology [that] uses a small polymer film applied to the inner lining of the cheek for rapid drug administration." *See* Ex. F (BDSI BEMA webpage); *see also* Ex. C (BDSI 2020 10-K SEC Filing) at p. 13; Ex. I ('177 patent at 11:1-15 ("The backing layer (e.g., a water-erodable non-adhesive backing layer) can further include at least one water erodable, film-forming polymer. This layer may optionally include a drug. The polymer or polymers can include polyethers and polyalcohols as well as hydrogen bonding cellulosic polymers having either hydroxyalkyl group Substitution or hydroxyalkyl group and alkyl group Substitution preferably with a moderate to high ratio of hydroxyalkyl to alkyl group. Examples include, but are not limited to, hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropyl lmethyl cellulose (HPMC), hydroxyethylmethyl cellulose (HEMC), polyvinyl alcohol (PVA), polyethylene glycol (PEG), polyethylene oxide (PEO), ethylene oxide-propylene oxide co polymers, ethylene oxide-propylene oxide co-polymers, and combinations thereof.").

iii. BDSI's BUNAVAIL buccal film contains carboxymethyl cellulose sodium, hydroxyethyl cellulose, and hydroxypropyl cellulose. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide;" *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

c. Claim 13 further recites "a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;"

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film contains buprenorphine hydrochloride and naloxone hydrochloride dihydrate as the active ingredients. *See id.* at "Medication Guide" ("**Active ingredients:** buprenorphine hydrochloride, naloxone hydrochloride dihydrate.").

iii. BDSI's BUNAVAIL buccal film uses BDSI's BEMA "technology [that] uses a small polymer film applied to the inner lining of the cheek for rapid drug administration." *See* Ex. F (BDSI BEMA webpage); *see also* Ex. C (BDSI 2020 10-K SEC Filing) at p. 13.

iv. BDSI's BUNAVAIL buccal film contains a substantially uniform distribution of buprenorphine hydrochloride and naloxone hydrochloride dihydrate within the polymer matrix at least because, in approving BUNAVAIL, the FDA assessed the content uniformity of BUNAVAIL and found it sufficiently uniform. *See, e.g.*, Ex. L (FDA Chemistry Review) at 8.

v. At least as described in paragraphs 30 and 32 above, BDSI's BUNAVAIL buccal film is formed using a manufacturing process which involves mixing the ingredients together to make a flowable wet blend, and then casting the viscoelastic, wet blend of ingredients, the film matrix, onto a carrier which travels through an oven to dry the film into a sheet which is then cut into individual units, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

vi. At least as described in paragraphs 30 and 32 above, BDSI's BUNAVAIL buccal film manufacturing process maintains a high level of drug content uniformity by using a controlled drying process, one aspect of which is to form a polymeric matrix and lock the active component in place so that it minimizes migration so that it does not result in a disuniform film, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

d. Claim 13 further recites "an anti-tacking agent selected from the group consisting of Vitamin E, Vitamin E TPGS, and sodium benzoate, wherein said tacking agent is present in amounts of about 0.01% to about 20% by weight of said film."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film contains sodium benzoate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

iii. At least as described in paragraphs 30 and 31 above, BDSI's BUNAVAIL buccal film contains sodium benzoate in amount of about 0.06% by weight of the film, the specific amount of which

Plaintiffs have a good faith basis to believe will be shown by further discovery.

37. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 33 of the '167 patent as follows:

a. Claim 33 recites "[t]he film of claim 13, wherein said at least one polymer is hydroxyethyl cellulose."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains hydroxyethyl cellulose. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

38. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 39 of the '167 patent as follows:

a. Claim 39 recites "[t]he film of claim 13, wherein said at least one polymer is carboxymethyl cellulose."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains carboxymethyl cellulose sodium. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

39. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 45 of the '167 patent as follows:

a. Claim 45 recites "[t]he film of claim 13, further comprising a buffer."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains monobasic sodium phosphate and sodium hydroxide. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

40. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 52 of the '167 patent as follows:

a. Claim 52 recites "[t]he film of claim 13, further comprising a sweetener."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains sodium saccharin. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

41. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 66 of the '167 patent as follows:

a. Claim 66 recites "[t]he film of claim 13, further comprising a flavoring agent."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains citrus blend favor. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

42. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 73 of the '167 patent as follows:

a. Claim 73 recites "[t]he film of claim 13, further comprising a coloring agent."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains yellow iron oxide. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

43. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 83 of the '167 patent as follows:

a. Claim 83 recites "[t]he film of claim 13, wherein the anti-tacking agent comprises sodium benzoate."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains sodium benzoate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

44. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 89 of the '167 patent as follows:

a. Claim 89 recites "[t]he film of claim 13, wherein the active component comprises an active selected from the group consisting of an opiate, opiate derivative, analgesic and combinations thereof."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains buprenorphine

hydrochloride and naloxone hydrochloride dihydrate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

45. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 95 of the '167 patent as follows:

a. Claim 95 recites "[a]n oral film for delivery of a desired amount of an active component comprising:"

i. BDSI's BUNAVAIL buccal film is "applied to the buccal mucosa." *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 2.1 *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at § 2.1.

ii. BDSI's BUNAVAIL buccal film delivers buprenorphine and naloxone in the desired dosage amount (2.1 mg / 0.3 mg, 4.2 mg / 0.7 mg, or 6.3 mg / 1 mg (buprenorphine/naloxone)) in an "oral transmucosal form." *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 11 (Description); *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at § 11.

iii. BDSI's BUNAVAIL buccal film contains buprenorphine hydrochloride and naloxone hydrochloride dihydrate as the active ingredients. *See id.* at "Medication Guide" ("**Active ingredients:** buprenorphine hydrochloride, naloxone hydrochloride dihydrate.").

b. Claim 95 further recites "an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethyl cellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;"

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film uses BDSI's BEMA "technology [that] uses a small polymer film applied to the inner lining of the cheek for rapid drug administration." *See* Ex. F (BDSI BEMA webpage); *see also* Ex. C (BDSI 2020 10-K SEC Filing) at p. 13; Ex. I ('177 patent at 11:1-15 ("The backing layer (e.g., a water-erodable non-adhesive backing layer) can further include at least one water erodable, film-forming polymer. This layer may optionally include a drug. The polymer or polymers can include polyethers and polyalcohols as well as hydrogen

bonding cellulosic polymers having either hydroxyalkyl group Substitution or hydroxyalkyl group and alkyl group Substitution preferably with a moderate to high ratio of hydroxyalkyl to alkyl group. Examples include, but are not limited to, hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropyl lmethyl cellulose (HPMC), hydroxyethylmethyl cellulose (HEMC), polyvinyl alcohol (PVA), polyethylene glycol (PEG), polyethylene oxide (PEO), ethylene oxide-propylene oxide co polymers, ethylene oxide-propylene oxide co-polymers, and combinations thereof.").

iii. BDSI's BUNAVAIL buccal film contains carboxymethyl cellulose sodium, hydroxyethyl cellulose, and hydroxypropyl cellulose. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

c. Claim 95 further recites "at least one anti-tacking agent comprising sodium benzoate;"

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film contains sodium benzoate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

d. Claim 95 further recites "a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;"

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film contains buprenorphine hydrochloride and naloxone hydrochloride dihydrate as the active ingredients. *See id.* at "Medication Guide" ("**Active ingredients:** buprenorphine hydrochloride, naloxone hydrochloride dihydrate.").

iii. BDSI's BUNAVAIL buccal film uses BDSI's BEMA "technology [that] uses a small polymer film applied to the inner

lining of the cheek for rapid drug administration." *See* Ex. F (BDSI BEMA webpage); *see also* Ex. C (BDSI 2020 10-K SEC Filing) at p. 13.

iv. BDSI's BUNAVAIL buccal film contains a substantially uniform distribution of buprenorphine hydrochloride and naloxone hydrochloride dihydrate within the polymer matrix at least because, in approving BUNAVAIL, the FDA assessed the content uniformity of BUNAVAIL and found it sufficiently uniform. *See, e.g.,* Ex. L (FDA Chemistry Review) at 8.

v. At least as described in paragraphs 30 and 32 above, BDSI's BUNAVAIL buccal film is formed using a manufacturing process which involves mixing the ingredients together to make a flowable wet blend, and then casting the viscoelastic, wet blend of ingredients, the film matrix, onto a carrier which travels through an oven to dry the film into a sheet which is then cut into individual units, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

vi. At least as described in paragraphs 30 and 32 above, BDSI's BUNAVAIL buccal film manufacturing process maintains a high level of drug content uniformity by using a controlled drying process, one aspect of which is to form a polymeric matrix and lock the active component in place so that it minimizes migration so that it does not result in a disuniform film, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

e. Claim 95 further recites "wherein said film is self-supporting and the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film is self-supporting at least because it is able to maintain its integrity and structure in the absence of a separate support when the film is removed from the foil package and applied directly against the cheek and left in place until the entire film dissolves. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at § 2.2 "Method of Administration," § 16 "How Supplied/Storage and Handling."

iii. BDSI's BUNAVAIL buccal film contains buprenorphine

hydrochloride and naloxone hydrochloride dihydrate that is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit does which do not vary by more than 10% of said desired amount of buprenorphine hydrochloride at least because, in approving BUNAVAIL, the FDA assessed the content uniformity of BUNAVAIL and found it sufficiently uniform. Plaintiffs have a good faith basis to believe that the specific content uniformity of BDSI's BUNAVAIL buccal film will be shown by further discovery. *See, e.g.,* Ex. L (FDA Chemistry Review) at 8.

46. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 96 of the '167 patent as follows:

a. Claim 96 recites "[t]he film of claim 95, further comprising a component selected from the group consisting of citric acid, propylene glycol, a sweetener, a preservative, a coloring agent, a flavor and combinations thereof."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains citric acid, citrus blend flavor, propylene glycol, propylparaben, yellow iron oxide, and sodium saccharin. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

47. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 97 of the '167 patent as follows:

a. Claim 97 recites "[t]he film of claim 95 further comprising an opiate or opiate derivative."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains buprenorphine

hydrochloride and naloxone hydrochloride dihydrate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

48. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 98 of the '167 patent as follows:

a. Claim 98 recites "[t]he film of claim 95 further comprising an analgesic."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains buprenorphine hydrochloride and naloxone hydrochloride dihydrate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

49. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 100 of the '167 patent as follows:

a. Claim 100 recites "[t]he film of claim 95 further comprising vitamin E acetate."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains vitamin E acetate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

50. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 103 of the '167 patent as follows:

a. Claim 103 recites "[t]he film of claim 95 further comprising a buffer."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains monobasic sodium phosphate and sodium hydroxide. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

51. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 107 of the '167 patent as follows:

a. Claim 107 recites "[t]he film of claim 96 wherein the sweetener comprises sodium saccharin."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 96 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains sodium saccharin. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

52. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 108 of the '167 patent as follows:

a. Claim 108 recites "[t]he film of claim 95 further comprising polyacrylic acid."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 95 of the '167 patent for the reasons identified in paragraph 45, above.

iii. BDSI's BUNAVAIL buccal film contains polycarbophil. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

53. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 117 of the '167 patent as follows:

a. Claim 117 recites "[t]he film of claim 13, wherein the anti-tacking agent is present in an amount sufficient to impart reduced film-to-film coefficient of friction."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains sodium benzoate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

iv. At least as described in paragraphs 30 and 31 above, BDSI's BUNAVAIL buccal film contains sodium benzoate in an amount sufficient to impart reduced film-to-film coefficient of friction at least because BDSI's BUNAVAIL buccal film is manufactured in a manner where the film has reduced adherence to the film itself, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

54. Furthermore, BDSI's BUNAVAIL buccal film satisfies all elements of Claim 118 of the '167 patent as follows:

a. Claim 118 recites "[t]he film of claim 13, wherein the anti-tacking agent is present in an amount sufficient to yield a film with a coefficient of friction which reduces adhesion of the film to adjacent surfaces during processing."

i. BDSI's BUNAVAIL buccal film literally infringes this limitation.

ii. BDSI's BUNAVAIL buccal film literally infringes claim 13 of the '167 patent for the reasons identified in paragraph 36, above.

iii. BDSI's BUNAVAIL buccal film contains sodium benzoate. *See* Ex. G (June 6, 2014 FDA Prescribing Information) at "Medication Guide"; *see also* Ex. E (March 4, 2021 FDA Prescribing Information) at "Medication Guide."

iv. At least as described in paragraphs 30 and 31 above, BDSI's BUNAVAIL buccal film contains sodium benzoate in an amount sufficient to impart reduced film-to-film coefficient of friction at least because BDSI's BUNAVAIL buccal film is manufactured in a manner where the film has reduced adherence to adjacent surfaces during manufacturing, the specific details of which Plaintiffs have a good faith basis to believe will be shown by further discovery.

55. Plaintiffs reserve the right to further amend and/or supplement these allegations following BDSI's production of documents regarding the BUNAVAIL buccal film, BDSI's disclosure of any non-infringement or invalidity position, the Court's determination of the meaning of any disputed terms, and/or any other development in this litigation that would make such supplementation necessary or appropriate.

56. Plaintiffs have not granted a license to the '167 patent or given any other authority to BDSI—or to anyone else—to make, use, sell, and/or offer for sale the BUNAVAIL buccal film.

57. On information and belief, Defendants know (a) that the BUNAVAIL buccal film is especially made or adapted for use in infringing one or more claims of the '167 patent and (b) that the BUNAVAIL product is not suitable for any substantial non-infringing uses.

58. On information and belief, and according to BDSI's SEC annual 10-K financial filings for years between 2014 and 2020, BDSI had net sales of the BUNAVAIL buccal film of at least $31,889,000 from the launch of BUNAVAIL in 2014 through December 2020.

59. BDSI's infringement of the '167 patent has caused and will continue to cause Plaintiffs irreparable injury and harm for which there is no adequate remedy at law unless and until BDSI is permanently enjoined by this Court from infringing.

60. As a result of BDSI's infringing activities, Plaintiffs have suffered and will continue to suffer damages in an amount yet to be determined. Under 35 U.S.C. §§ 283 and 284, Plaintiffs are entitled to recover damages in an amount to be proven at trial, and in any event not less than a

reasonable royalty, together with interests and costs, as well as permanent injunctive relief.

61. BDSI's infringement has been committed with full knowledge of Plaintiffs' rights in the '167 patent since at least (i) BDSI's first making, using, offering to sell, and/or selling BUNAVAIL or (ii) September 22, 2014. Such acts constitute willful and deliberate infringement, entitling Plaintiffs to enhanced damages and reasonable attorneys' fees.

COUNT II
(Indirect Infringement of the U.S. Patent No. 8,765,167)

62. Plaintiffs incorporates each of the preceding paragraphs 1-61 as if fully set forth herein.

63. The use or administration of any of the dosage strengths of BDSI's BUNAVAIL buccal film by healthcare professionals and/or patients has directly infringed and continues to infringe at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

64. For at least the reasons identified in paragraphs 36-54 above, BDSI's BUNAVAIL buccal film meets all of the limitations of at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

65. Through its commercial manufacture, sale, offer for sale, and instructions for use of each of the dosage strengths of BDSI's BUNAVAIL buccal film and other actions, BDSI has indirectly infringed and continues to indirectly infringe under 35 U.S.C. §§ 271(b) and (c) at least the following valid and enforceable claims of the '167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

66. BDSI has had knowledge of the '167 patent since at least September 22, 2014, including knowledge of claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118 of the '167 patent.

67. BDSI has induced and continues to induce infringement of the ’167 patent by affirmatively aiding, abetting, urging, or encouraging direct infringement by healthcare professionals and/or patients, by, *inter alia*, instructing them to use BDSI’s infringing BUNAVAIL buccal film. BDSI has explicitly instructed and continues to instruct healthcare professionals and/or patients to use its infringing BUNAVAIL buccal film by, *inter alia*, providing Prescribing Information and other instructions that instruct healthcare professionals and/or patients to use the BUNAVAIL buccal film, which includes all of the elements of at least the following valid and enforceable claims of the ’167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

68. Since at least September 22, 2014, BDSI has had knowledge that the induced acts would constitute infringement of the ’167 patent and has specifically intended to cause such infringement. BDSI has, *inter alia*, intentionally provided Prescribing Information and other instructions to healthcare professionals and/or patients that instruction the healthcare professionals and/or patients to use the infringing BUNAVAIL buccal film, with knowledge of the ’167 patent and with knowledge that use by the healthcare professional and/or patient of BUNAVAIL buccal film directly infringes at least the following valid and enforceable claims of the ’167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118. BDSI has also, *inter alia*, intentionally, on information and belief, provided manufacturers of its BUNAVAIL buccal film with manufacturing and other instructions for manufacturing the BUNAVAIL buccal film, with knowledge of the ’167 patent and with knowledge that manufacturing the BUNAVAIL buccal film directly infringes at least the following valid and enforceable claims of the ’167 patent: 19-25.

69. BDSI’s affirmative acts, including its commercial manufacture, sale, offer for sale,

and/or its provision of instructions for BUNAVAIL buccal film to healthcare professionals and/or patients, have induced and/or caused, and continue to induce and/or cause, direct infringement by manufacturers, healthcare professionals and/or patients.

70. BDSI has contributed to, and continues to contribute to, infringement of at least the following valid and enforceable claims of the ’167 patent: 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118.

71. BDSI’s BUNAVAIL buccal film constitutes a material part of the invention covered by the claims of the ’167 patent because, *inter alia*, it includes all of the elements of the oral films or manufacturing methods of the oral film of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118 of the ’167 patent.

72. Since at least September 22, 2014, BDSI has known that its BUNAVAIL buccal film is especially made or especially adapted for use in the infringement of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118 of the ’167 patent.

73. Since at least September 22, 2014, BDSI has known that there is no substantial non-infringing use for its BUNAVAIL buccal film.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

1. A judgment holding that BDSI have infringed the ’167 patent under 35 U.S.C. § 271;

2. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial, including both pre-judgment and post-judgment interest;

3. A permanent injunction, restraining and enjoining BDSI, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert

with them, from engaging in, causing, contributing to, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or other products, claimed in the ’167 patent;

4. A judgment finding that BDSI’s infringement of the ’167 patent has been willful and awarding treble damages under 35 U.S.C. § 284;

5. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys’ fees; and

6. Any and all other relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Aquestive requests a trial by jury on all triable issues.

Date: May 18 , 2021. Respectfully submitted,

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